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of Correction

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FROM: Paul D. Bianco, Ph.D.

REFERENCE: 780-A03-021-4

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Patentee: Peter M. Bonutti

Confirmation No.: 1470

Application No.: 10/755,995

Group Art Unit: 3731

Patent No.: 7,001,358

Examiner: D. Reip

Filed: January 13, 2004

Attorney Docket No: 780-A03-021-4

Issued: February 21, 2006

For: **JOINT SPACER WITH COMPARTMENT FOR  
ORTHOBIOLOGIC MATERIAL**

1. Request for Certificate of Correction of Patent (2 pgs)
2. Certificate of Correction (duplicate)
3. Copy of Response to Office Action (10 pgs)

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On April 24, 2006

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Patentee: Peter M. Bonutti

Confirmation No.: 1470

Application No.: 10/755,995

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For: JOINT SPACER WITH COMPARTMENT FOR  
ORTHOBIOLOGIC MATERIAL

**REQUEST FOR CERTIFICATE OF CORRECTION OF PATENT  
UNDER 37 C.F.R. § 1.322**

ATTN:

Certificate of Corrections Branch  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313

Sir:

It is noted that an error appears in the above-identified patent. The exact location and nature of this error is as follows:

Column 23, Claim 30, Line 60 Change "tick" to --thick--

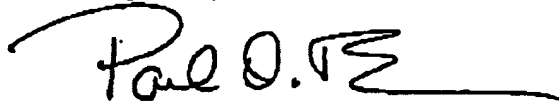
A copy of the Amendment for this case filed August 24, 2005 is enclosed. As claim 31, which issued as claim 30, was allowed in the form presented in this Amendment, issued claim 30 should read as found in the Amendment and should be corrected as noted above. Additionally, it is respectfully submitted that this error is of a clerical error and attributable solely to Office

**MAY 2 2006**

mistake. Accordingly, a Certificate of Correction is requested. Attached hereto in duplicate is Form PTO-1050 with at least one copy being suitable for printing. Please send the Certificate of Correction to the undersigned at the address noted. If there are any questions regarding this Request, a telephone call to the undersigned would be appreciated since this should expedite issuance of the Certificate.

As this error is solely attributable to an Office mistake, no fee is believed to be due. However, should any fee be due, please charge the appropriate fee to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 780-A03-021-4)

Respectfully submitted,



Paul D. Bianco, Reg. #43,500

Enclosures

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MAY 2 2006

PTO/SB/44 (04-04)

Approved for use through 04/30/2007. OMB 0851-0033

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(Also Form PTO-1050)**UNITED STATES PATENT AND TRADEMARK OFFICE  
CERTIFICATE OF CORRECTION**

PATENT NO. : 7,001,385

DATED : February 21, 2006

INVENTOR(S) : Peter M. Bonutti

It is certified that error appears in the above-identified patent and that said Letters Patent  
is hereby corrected as shown below:

Column 23

Line 60, change "tck" to -thick-

MAILING ADDRESS OF SENDER: Paul D. Bianco  
Fleit, Kain, Gutman, Gibbons,  
Bongini & Bianco P.L.  
21355 East Dixie Highway, Suite 115  
Miami, FL 33180

PATENT NO. 7,001,386

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This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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(Also Form PTO-1050)**UNITED STATES PATENT AND TRADEMARK OFFICE  
CERTIFICATE OF CORRECTION**

PATENT NO. : 7,001,385

DATED : February 21, 2006

INVENTOR(S) : Peter M. Bonutti

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 23

Line 60, change "tick" to --thick--

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Fleit, Kain, Gutman, Gibbons,  
Bongini & Bianco P.L.  
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PATENT NO. 7,001,385

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In re application of: P. Bortus Application No.: 10/726,885 Filed: January 13, 2004 For: JOINT SPACER WITH COMPARTMENT FOR ORTHODONTIC MATERIAL	Confirmation No.: 1470 Group A1 Unit: 3701 Examiner: D. Rolp Attorney Docket No.: TEO-A03-021-4
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): P. Bonutti

Attorney Docket No: 780-A03-021-4

Application No.: 10/755,995

Confirmation No.: 1470

Filed: January 13, 2004

Group Art Unit: 3731

For: JOINT SPACER WITH COMPARTMENT FOR  
ORTHOBIOLGIC MATERIAL

Examiner: D. Reip

RESPONSE TO OFFICE ACTION

Mail Stop AMENDMENT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Introductory Comments

Dear Sir:

In reply to the Office Action mailed May 26, 2005, please enter the following amendments and remarks into the file for the above-identified application. Applicant submits these amendments and remarks serve to clarify the present invention and are independent of patentability.

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ATTENTION EXAMINER D. Reip

On August 24, 2005

Dinah Fuentes

Name of Person Transmitting Facsimile

  
Signature of Person Transmitting Facsimile

2 2006

Applicant: P. Bonutti  
Application No.: 10/755,995  
Examiner: D. Reip

Amendments to the Claims

1. (Currently amended) An implantable device for changing the spatial relationship between first and second bones, the device comprising a wedge body configured and dimensioned for insertion into a joint located between the first and second bones, and the wedge body having a thin end portion, a thick end portion, a first major side surface which extends from the thin end portion to the thick end portion, a second major side surface which intersects the first major side surface to form an edge at the thin end portion and extends from the thin end portion to the thick end portion, and a minor side surface which extends between the first and second major side surfaces and tapers from the thick end portion to the thin end portion, the wedge body having a compartment containing a bone growth inducing material, wherein the bone growth inducing material includes a bone morphogenic protein.

2. (Original) The device of claim 1 wherein the bone growth inducing material includes demineralized bone.

**COPY**

3. (Original) The device of claim 2 wherein the demineralized bone is a powder.

4. (Original) The device of claim 1 wherein the bone growth inducing material includes collagen.

5. (Original) The device of claim 4 wherein the collagen is in the form of apatite compositions with collagen.

6. (Original) The device of claim 4 wherein the bone growth inducing material includes demineralized bone.

7. (Original) The device of claim 6 wherein the demineralized bone is a powder.

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Applicant: P. Bonatti  
Application No.: 10/755,995  
Examiner: D. Reip

8. (Currently amended) The device of claim 4 wherein the wedge body is made of a porous material.

9. (Original) The device of claim 8 wherein the porous material includes cavities with at least some of the cavities containing a bone growth promoting material.

10. (Currently amended) The device of claim 1 further including fastener means for fixedly connecting the wedge body to at least one of the first and second bones.

11. (Original) The device of claim 10 wherein the fastener means includes at least one screw.

12. (Currently amended) The device of claim 10 wherein the fastener means includes a first connector configured and dimensioned to connect the wedge body to the first bone and a second connector configured and dimensioned to connect the wedge body to the second bone.

**COPY**

13. (Currently amended) A spinal implant for insertion in a joint located between first and second vertebrae, the implant comprising a wedge member configured and dimensioned for insertion into the joint, and the wedge member having a thin end portion, a thick end portion, a first major side surface which extends from the thin end portion to the thick end portion, a second major side surface which intersects the first major side surface to form an edge at the thin end portion and extends from the thin end portion to the thick end portion, and a minor side surface which extends between the first and second major side surfaces and tapers from the thick end portion to the thin end portion, the wedge member having a compartment containing a bone growth inducing material, wherein the bone growth inducing material includes a bone morphogenic protein.

14. (Original) The implant of claim 13 wherein the bone growth inducing material includes demineralized bone.

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Applicant: P. Bonutti  
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15. (Original) The implant of claim 14 wherein the demineralized bone is a powder.
16. (Original) The implant of claim 13 wherein the bone growth inducing material includes collagen.
17. (Original) The implant of claim 16 wherein the collagen is in the form of apatite compositions with collagen.
18. (Original) The implant of claim 16 wherein the bone growth inducing material includes demineralized bone.
19. (Original) The implant of claim 18 wherein the demineralized bone is a powder.
20. (Original) The implant of claim 16 wherein the wedge member is made of a porous material.
21. (Original) The implant of claim 20 wherein the porous material includes cavities with at least some of the cavities containing a bone growth promoting material.
22. (Currently amended) The implant of claim 13 further including fastener means for fixedly connecting the wedge member body to at least one of the first and second vertebrae.
23. (Original) The implant of claim 22 wherein the fastener means includes at least one screw.
24. (Original) The implant of claim 22 wherein the fastener means includes a first connector configured and dimensioned to connect the wedge member to the first vertebra and a second connector configured and dimensioned to connect the wedge member to the second vertebra.
25. (Currently amended) The implant of claim 13 wherein the wedge member tapers from the thick trailing end portion to the thin leading end portion.

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26. (Original) The implant of claim 25 wherein the wedge member is made of a biocompatible metallic material.

27-29. (Canceled)

30. (Original) The implant of claim 13 wherein a bone growth promoting material is disposed on the wedge member.

31. (Currently amended) A method of changing the spatial relationship between first and second bones, the method comprising:

providing an implantable device including an internal compartment, the implantable device having a thin end portion, a thick end portion, a first major side surface which extends from the thin end portion to the thick end portion, a second major side surface which intersects the first major side surface to form an edge at the thin end portion and extends from the thin end portion to the thick end portion, and a minor side surface which extends between the first and second major side surfaces and tapers from the thick end portion to the thin end portion;

placing a bone growth inducing material into the internal compartment, the bone growth inducing material including a bone morphogenic protein; and

inserting the implantable device into a joint located between the first and second bones.

**COPY**

32. (Original) The method of claim 31 further comprising connecting the implantable device to at least one of the first and second bones.

33. (Currently amended) The method of claim 31 wherein inserting the implantable device into the joint located between the first and second bones comprises:

positioning the thin an end portion of the implantable device in the joint located between the first and second bones; and

expanding at least a portion of the joint by moving the implantable device into the joint to

Applicant: P. Bonutti  
Application No.: 10/755,995  
Examiner: D. Reip

apply a force against the first and second bones with the implantable device such that the spatial relationship between a first central longitudinal axis of the first bone and a second central longitudinal axis of the second bone changes as the implantable device is moved into the joint.

34. (Original) The method of claim 31 wherein the bone growth inducing material includes demineralized bone.

35. (Original) The method of claim 34 wherein the demineralized bone is a powder.

36. (Original) The method of claim 34 wherein the bone growth inducing material includes collagen.

37. (Original) The method of claim 36 wherein the collagen is in the form of apatite compositions with collagen.

**COPY**

38. (Original) The method of claim 36 wherein the implantable device is made of a porous material.

39. (Original) The method of claim 38 wherein the porous material includes cavities with at least some of the cavities containing a bone growth promoting material.

40. (Currently amended) The method of claim 31 wherein the ~~thick implantable device~~ comprises a first end portion has having a first thickness and the thin a second end portion ~~opposite the first end portion and having~~ has a second thickness less than the first thickness.

41. (Currently amended) The method of claim 40 wherein inserting the implantable device into the joint located between the first and second bones comprises:

positioning the thin second end portion of the implantable device in the joint located between the first and second bones; and

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Application No.: 10/755,995  
Examiner: D. Reip

expanding at least a portion of the joint located between the first and second bones by moving the implantable device into the joint to apply a force against the first and second bones with the implantable device, such that the spatial relationship between a first central longitudinal axis of the first bone and a second central longitudinal axis of the second bone changes as the implantable device is moved into the joint.

42. (Original) The method of claim 31 wherein the first and second bones are first and second vertebrae.

43. (New) The device of claim 1 wherein the bone growth inducing material includes a bone morphogenic protein.

44. (New) The implant of claim 13 wherein the bone growth inducing material includes a bone morphogenic protein.

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Applicant: P. Bonutti  
Application No.: 10/755,995  
Examiner: D. Reip

### Remarks

Claims 1-26 and 30-44 are pending in the application and are presented for the Examiner's review and consideration. Claims 1, 8, 10, 12, 13, 22, 25, 31, 33, 40, and 41 have been amended, and claims 27-29 have been canceled. Claims 43 and 44 have been added. Applicant believes the claim amendments and accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

### Claim Rejections

Claims 1, 10-13, 22-26, 30-33, and 40-42 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,609,635 to Michelson ("Michelson"). Claims 2-9, 14-21, and 34-39 were rejected under 35 U.S.C. §103(a) as being unpatentable over Michelson in view of U.S. Patent No. 4,394,370 to Jefferies ("Jefferies"). In response, Applicant respectfully submits that these rejections should be withdrawn.

To further define the present invention, Applicant has amended independent claims 1, 13, and 31 to include, *inter alia*, a wedge body/member having a thin end portion, a thick end portion, a first major side surface which extends from the thin end portion to the thick end portion, a second major side surface which intersects the first major side surface to form an edge at the thin end portion and extends from the thin end portion to the thick end portion, and a minor side surface which extends between the first and second major side surfaces and tapers from the thick end portion to the thin end portion. Applicant contends that Michelson, alone or in combination with Jefferies, fails to teach or suggest all the elements of the claims 1, 13, and 31. Based on their dependencies, Applicant further contends that claims 2-12, 14-26, 30, and 32-44 are patentable as well.

### Conclusion

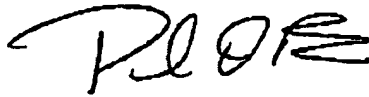
In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be

Applicant: P. Bonutti  
Application No.: 10/755,995  
Examiner: D. Reip

appreciated since this should expedite the prosecution of the application for all concerned.

No fee is believed to be due for this submission. However, please charge any required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 780-A02-021-4).

Respectfully submitted,



Paul D. Bianco, Reg. # 43,500

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